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[REDACTED] EXAMINER

CHAKRABARTI, ARUN K

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1634

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/043,995	Applicant(s) Zhu
	Examiner Arun Chakrabarti	Art Unit 1634
		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Jan 11, 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- 4) Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above, claim(s) 6, 7, and 9 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5 and 8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Disposition of Claims

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: *Detailed Action*

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-5 and 8, drawn to gene chip, classified in class 536, subclass 22.1.
 - II. Claims 6 , 7, and 9, drawn to fluorescence probes, classified in class 252 , subclass 301.16 .
2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product of reactive media including fluorescence probes, is deemed to be useful as detection tools of proteins, antigen-antibody complex and lipids and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Patrea Pabst on August 18, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-5 and 8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-7 and 9 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b), as being drawn to a non-elected invention.

Priority

5. In absence of a translated copy of the foreign application, priority of February 21, 2001 is not granted. Applicant gets the priority only of the filing date January 11, 2002. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CAR 1.55 in reply to this action.

Specification

6. Claims 1, 2, 4 and 8 are objected to as the claims recite more than one sentence per each claim. See MPEP 608.01 (m): "Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See Fressola v. Manbeck, 36 USPQ2d 1211 (D.D.C. 1995)." Appropriate correction is required.

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Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rejected over the recitation of the phrase, "oncereaction". In absence of a definition of the term in the specification, it is not clear if a special type of reaction is claimed or only one reaction is claimed or both are claimed. The metes and bounds of the claim are vague and indefinite.

Regarding claim 2 , the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The term "a little amount" in claim 2 is a relative term which renders the claim indefinite. The term "a little amount" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. .

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Claim 4 recites the future tense “will be” on lines 3 and 4. It is not clear if the process steps will be performed later or already it has been done or the gene-chip is capable of performing such steps. In absence of any working example and clear recitation of a process step, the metes and bounds of the claim are vague and indefinite.

9. Claims 1-5 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. While the applicant claims detection of more than 100 kinds of gene variants, there is no working example of performing any PCR reaction and detection of any kind of gene variants such as gene mutation, deletion or rearrangement in just one reaction. The specification as well as the claims only describe in passive voice (with special emphasis to “can be performed” and “will be employed” and so forth) and in an imaginary language what this gene chip is capable of doing rather than setting forth any clear working example. There is neither a diagram nor a clear description to demonstrate 100-20,000 Micro-reactors of the claimed invention. In absence of a clear description of what the claimed “gene chip” is, the claims are rejected because the claimed invention was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Northrup et al. (U.S. Patent 5,589,136) (December 31, 1996).

Northrup et al teaches a gene chip, characterized by 100-20,000 Micro-reactors (MRS) (384 to be precise) on the same plane in which PCR reaction can be performed (Figures 10A-B and Column 12, lines 5-54).

Northrup et al teaches a gene chip, wherein MRS are connected by a set of pipeline, through which a sample can flow into all the MRS (Figures 4 and 11 and Column 12, lines 39-44 and claims 15-18).

Northrup et al teaches a gene chip, wherein a set of reactive media exits in each of the MR and PCR can be performed simultaneously under the same condition and real-time quantification can be carried out by detecting the change of the optical density in the MR through its top surface, which is transparent (Figures 3 and 10A).

Northrup et al teaches a gene chip, wherein PCR can be performed simultaneously, after the infusion of a little amount of genomic DNA or degenerative cells from human beings, animals or plants into the MR and therefore more than 100 kinds of gene variants such as gene mutation,

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gene deletion or gene rearrangement can be detected in just one reaction (Figure 9 and Column 10, line 28 to Column 12, line 39).

Northrup et al inherently teaches a gene chip, wherein the material is silica or plastic which is able to endure the temperature of 0-99 degree Celsius for up to 24 hours (Column 12, lines 37-38). This inherency is deduced from the fact that silicones, used by Northrup, has broad spectrum of temperature withstanding capability and widely used in laboratories and to produce computer accessories.

Northrup et al teaches a gene chip, wherein the PCR primers in the reactive media are made up with primers to amplify multifarious functional genes, immobilized on the bottom of the MRs after being mixed (Figure 19 and Column 14, lines 43-55).

Northrup et al teaches a gene chip, wherein the top surface of the MRs is transparent (optical window used by Northrup) through which the optical density of the fluorescence or other dyes in the MRs can be detected which is proportional to the amount of the PCR product (Figures 10A, 15 and 16 and Column 13, line 4 to Column 14, line 55).

Northrup et al inherently teaches a gene chip, wherein the image collector will monitor the real time change of the optical density and transfer the data collected into the image analysis system of the computer software (Claim 20 and Figures 3 and 9 and Column 9, lines 1-18). This inherency is deduced from the fact that “computer interface” used by Northrup (Column 9, line 8) is capable of monitoring the real time change of the optical density and transfer the data collected into the image analysis.

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Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 4 is rejected under 35 U.S.C. 103(a) as being obvious over Northrup et al. (U.S.

Patent 5,589,136) (December 31, 1996) in view of Sager et al. (U.S. Patent 6,518,747 B2)

(February 11, 2003).

Northrup et al teaches the gene chip of claims 1-3, 5 and 8 as described above.

Northrup et al does not teach the gene chip, wherein the reagents in the active media are adsorbed by the magnetic beads whose diameters are in nanometer level and immobilized on the bottom of reaction chamber by magnetic force and can be stirred to accelerate the reaction.

Sager et al. teaches the gene chip, wherein the reagents in the active media are adsorbed by the magnetic beads whose diameters are in nanometer level and immobilized on the bottom of reaction chamber by magnetic force and can be stirred to accelerate the reaction (Abstract, Figures 1-3 and Column 1, line 62 to Column 2, line 11).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the device, wherein the reagents in the active media are adsorbed by the magnetic beads whose diameters are in nanometer level and

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immobilized on the bottom of reaction chamber by magnetic force and can be stirred to accelerate the reaction of Sager et al. into the gene chip of Northrup et al., since Sager et al. states, “The magnetic particles then become “handles” by which the objects can be moved or immobilized using a magnetic gradient, usually provided by a strong permanent magnet. (Column 2, lines 5-8)”. By employing scientific reasoning, an ordinary artisan would have combined and substituted the device, wherein the reagents in the active media are adsorbed by the magnetic beads whose diameters are in nanometer level and immobilized on the bottom of reaction chamber by magnetic force and can be stirred to accelerate the reaction of Sager et al. into the gene chip of Northrup et al. in order to improve the quantity and quality of PCR reactions. An ordinary practitioner would have been motivated to combine and substitute the device, wherein the reagents in the active media are adsorbed by the magnetic beads whose diameters are in nanometer level and immobilized on the bottom of reaction chamber by magnetic force and can be stirred to accelerate the reaction of Sager et al. into the gene chip of Northrup et al., in order to achieve the express advantages, as noted by Sager et al., of magnetic particles that become “handles” by which the objects can be moved or immobilized using a magnetic gradient, usually provided by a strong permanent magnet.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to

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Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group LIE Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

September 3, 2003

Arun Kr. Chakrabarti
ARUNK. CHAKRABARTI
PATENT EXAMINER

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